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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/667,056

09/22/2003

Sean McFerran

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EXAMINER

GRAY, PHILLIP A

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

10/13/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/667,056	Applicant(s) MCFERRAN, SEAN	
	Examiner Phillip Gray	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 and 15-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-20 is/are allowed.
- 6) ☒ Claim(s) 13, 15-17 and 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's communication of 7/22/2010. Currently claims 13,15-28 are pending and claims 13, 15-17, 21-28 stand rejected.

Response to Arguments

Applicant's arguments filed 7/22/2010 have been fully considered but they are not persuasive. Applicants argue that both Pfenninger and Allman fails to teach, concerning the new amended claims, "wherein when no guidewire is provided through the passage, the single lumen is substantially fluid tight from the proximal end of the elongate shaft to the opening at the distal end of the elongate shaft".

Examiner is reading this limitation as a functional/operational limitation. The same reading of the limitation for claim 27 (since the "passage is configured to..") is being read as a functional limitation. Therefore the limitation is not a positive limitation but only requires the ability to so perform. Further the "wherein " statement does not define any structure and accordingly can not serve to distinguish. The examiner is of the position that Allman would teach this fluid tight ability when no guide wire is in the passageway. Evidence of this can be found at Allman paragraphs at column 2 lines 60 through column 3 line 22; column 8 lines 1-47; and column 10 line 62 through column 11 line 52, and further see slit and sheaths shown in figures 3-8.

Further is it examiners position that both Pfenninger and Allman discloses "a slit extending at an angle such that the slit has a depth measured from the inner surface to the outer surface of the polymer sheath that is greater than the thickness of the wall of

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the polymer sheath, wherein the slit is defined between a first edge of the polymer sheath and a second edge of the polymer sheath facing the first edge, wherein each of the first edge and the second edge extend from the outer surface to the inner surface of the polymer sheath, and wherein the first edge and the second edge are in contact with each other when no guidewire is extended through the passage". Both Pfenninger and Allman teach this as would any slit on an angle less than 90 degree to the outer surface (see Pfenninger figure 3 and Allman figure 4B or 4C).

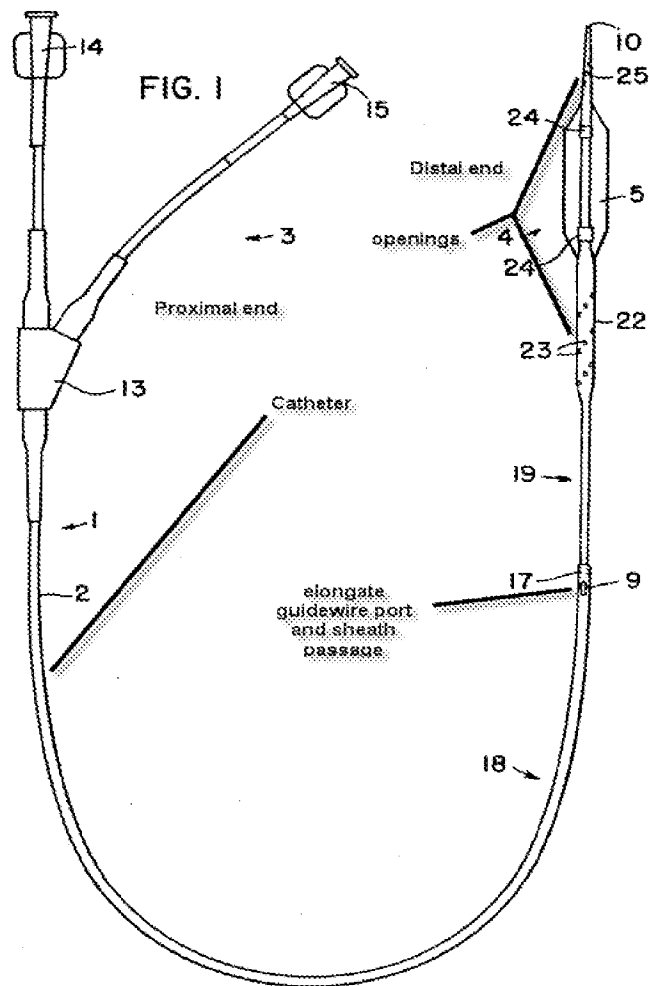
Claim Rejections - 35 USC § 103(2nd time)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

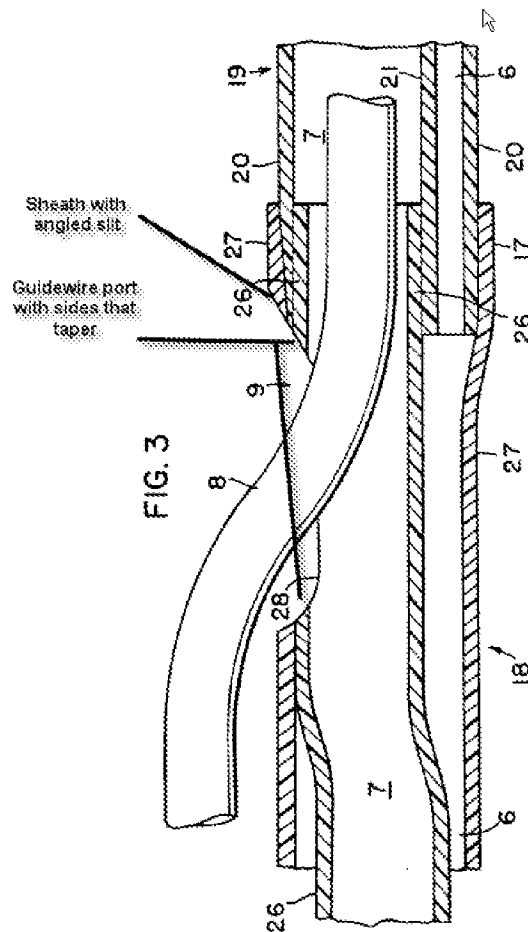
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 15-17, and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfenninger (U.S. Patent Number 5,306,247) in view of Allman et al. (U.S. Patent Number 6,346,093).

Pfenninger discloses a catheter (near 2) comprising an elongate shaft having a distal and proximal end fluidly connected to an opening (25/23) at the distal end of the elongate shaft, an elongate guidewire port (near 9), and a polymer sheet with a passage over the guidewire port (see marked up figure 1)

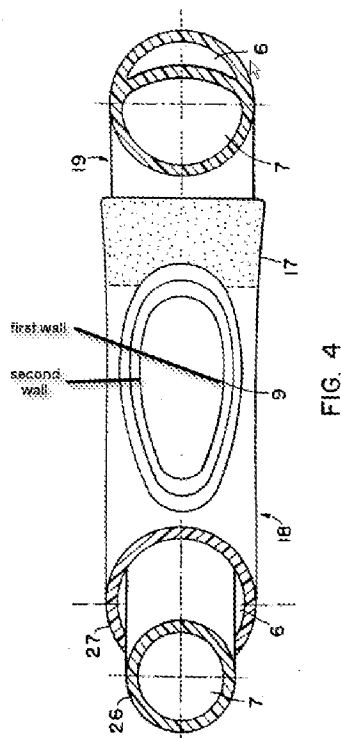


Further note the Sheath (27), angled slit see figure below, guidewire port (near 9 or 28) with tapered walls (see marked up figure 3 below).



Concerning claim 15-16, see near 27 in figure 3.

Concerning claim 23 see marked up figure 4 below. Concerning claim 24 note slit length is larger than port length. Concerning claim 25-26 note port near 28 tapered edges as in figures 3 and 4.



Pfenninger discloses the claimed invention except for the longitudinal angled slit configured to permit guidewire access through the guidewire port while maintaining a substantially fluid tight in use when no guide wire is provided. Allman teaches that it is known to use a longitudinal angled slit configured to permit guidewire access through the guidewire port while maintaining a substantially fluid tight in use when no guide wire is provided as set forth in paragraphs at column 8 lines 1-46 also see slit 118 in figure 4 and 4b or near 134 in figure 4c to provide and allow a guidewire to be radially slid into or out of the sheath assembly. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Pfenninger with a longitudinal angled slit as taught by Allman, since such a modification would

provide the system with a longitudinal slit for providing and allowing a guidewire to be radially slid into or out of the sheath assembly.

Concerning claim 21 and 22, Pfenninger discloses the claimed invention except for the length of the guide wire port is at least six times greater than the width. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the guidewire port have a length six times greater than the width, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Concerning claims 21-28 see response to applicants arguments above.
Concerning the claim language of “wherein when no guidewire is provided through the passage, the single lumen is substantially fluid tight from the proximal end of the elongate shaft to the opening at the distal end of the elongate shaft” see response to arguments above.

Allowable Subject Matter

Claims 18-20 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/
Examiner, Art Unit 3767

/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767